Remarks

Introduction

Claims 35-77 were pending. By way of this response, claims 46 and 66 have been amended, and claims 78-81 have been added. Support for the amendments to the claims can be found in the application as originally filed, and no new matter has been added. Accordingly, claims 35-81 are currently pending.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 35 and 52-53 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In short, the Office Action states that the claims include new matter since the subject matter of the claims is allegedly not described in the specification of the above-identified application.

Applicant traverses the rejection.

Applicant submits that the subject matter of claims 35, 52, and 53 is properly described in the specification of the above-identified application. For example, Example 7 (page 29) discusses in vivo release of the steroid, dexamethasone, from drug delivery systems which were formed from equal amounts of dexamethasone and PLGA. The in vivo release rates are provided in Table 8. Based on the description of the above-identified application, including Example 7, applicant submits that specification clearly describes implants without an added release modifier, and clearly describes the subject matter of claims 35, 52, and 53.

In view of the above, applicant submits that the subject matter of claims 35, 52, and 53 is sufficiently described in the specification of the above-identified patent application to comply with 35 U.S.C. § 112, first paragraph, and that these claims do not include new matter.

Rejections Under 35 U.S.C. § 103

Claims 35-77 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Wong et al. (U.S. Pat. No. 5,869,079; hereinafter Wong). Claims 48-50 and 68-70 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Wong in view of Guo et al. (U.S. Patent No. 6,217,895; hereinafter Guo).

Applicant traverses each of these rejections as it pertains to claims 35-81.

The Examiner states that a person of ordinary skill in the art would have been motivated to make modifications to the implants disclosed by Wong because different ocular conditions call for different medicaments. The Examiner further states that such modifications would result in "several formulations of implants, each formulation made for a specific ocular inflammation-mediated condition".

Applicant submits that the present claims are unobvious from and patentable over Wong, or the combination of Wong and Guo, because the references taken alone or in any combination do not disclose, teach, or suggest all of the elements recited in the present claims. For example, the references, taken alone or

in any combination, do not specifically disclose, teach, or even suggest, an intravitreal implant that is structured to deliver an anti-inflammatory agent to the vitreous of any eye in the specific amounts recited in the present claims.

In reference to the present claims, the implants of claims 35 and 52 are structured to deliver an amount of an anti-inflammatory agent sufficient to reach an in vivo concentration equivalent to at least about 0.05 μg/ml dexamethasone within about 48 hours and to maintain an in vivo concentration equivalent to at least about 0.03 μg/ml dexamethasone for at least about three weeks. The implants of claims 53 and 72 are structured to deliver the agent to the vitreous in an amount sufficient to reach an in vivo concentration equivalent to at least about 0.2 μg/ml dexamethasone within about 6 hours and to maintain an in vivo concentration equivalent to at least about 0.01 μg/ml dexamethasone for at least about three weeks. The implants of claim 73 have a total mass of about 800-1100 μg, and the implants release at least about 10% of the drug load within 1 week when measured under infinite sink conditions in vitro. The presently claimed implants have features that are not specifically disclosed, taught, or even suggested by Wong, or the combination of Wong and Guo.

It is well established that "a reference must be interpreted as a whole, and cannot be picked apart to deprecate an invention" (In re Fine, 837 F.2d 1071, 1075, (Fed. Cir. 1988)). "Particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed." (In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir.

1998) The obviousness test requires that the Examiner must show reasons that a person of ordinary skill in the art, when confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed. For example, the Examiner must show reasons that a person of ordinary skill in the art would modify Wong, with no knowledge of the present invention, to obtain implants that are structured to deliver the specific amounts of the anti-inflammatory agent recited in the present claims.

Applicant submits that such reasons have not been presented and do not exist. For example, the Office Action fails to identify any reason that a person of ordinary skill in the art would modify the teachings of Wong and obtain implants that deliver the specific amounts of an anti-inflammatory agent recited in the present claims.

The Examiner's general motivation in the Office Action that different ocular conditions call for different medicaments, and that modifications of the implants of Wong would result in "several formulations of implants, each formulation made for a specific ocular inflammation-mediated condition" provides no basis for a person of ordinary skill in the art to modify the teachings of Wong and obtain implants that deliver the specific amounts of the anti-inflammatory agent recited in the present claims. Simply put, there is no specific basis for modifying the teachings of Wong, or Wong and Guo, and obtaining implants providing the specific amounts of anti-inflammatory agents, as recited in the present claims.

Furthermore, applicant submits that even if the teachings of the references could be erroneously modified or combined, the resulting implants resulting from the modification of Wong, or of the combination of Wong and Guo, would be structured to deliver amounts of an anti-inflammatory agent that are different than recited in the present claims. As recited in the present claims, the present implants deliver specific amounts of an anti-inflammatory agent defined by certain numerical ranges. Therefore, the references taken alone, or in any combination, do not specifically disclose, teach, or even suggest all of the elements of the presently claimed implants.

In view of the above, applicant submits that the present claims, and independent claims 35, 52, 53, 72, and 73, are unobvious from and patentable over Wong, and over the combination of Wong and Guo, under 35 U.S.C. § 103.

In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present implants including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

Conclusion

In conclusion, applicant has shown that the present claims satisfy the requirements of 35 U.S.C. § 112, and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims,

that is claims 35-81 are allowable. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Respectfully submitted,

Date: 4/11/05

Frank J. Uxa
Registration No. 25,612
4 Venture, Suite 300
Irvine, California 92618
(949) 450-1750
(949) 450-1764 Facsimile